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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,544	03/19/2002	Laurent Di Costanzo	C1190/20009	7903

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EXAMINER

OH, SIMON J

ART UNIT PAPER NUMBER

1615

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,544

Applicant(s)

COSTANZO ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-39 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 21-39 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, and petition for extension of time, all received on 01 March 2004.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1 and 7 under 35 U.S.C. 112 is rendered moot with the cancellation of those claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-20 under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* in view of Schmitz *et al.* is rendered moot with the cancellation of those claims.

The rejection of Claims 1-20 under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* in view of Schmitz *et al.* and Valentine is rendered moot with the cancellation of those claims.

Claims 21-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* in view of Schmitz *et al.* and Valentine.

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The Liu *et al.* patent teaches pharmaceutical dosage forms for a rapidly disintegrating buccal tablet (See Column 1, Line 49 to Column 2, Line 3). The tablets dissolve in about 1 to about 40 seconds in an aqueous solution, which is typically saliva (See Column 2, Lines 45-51). Processes for making this tablet are disclosed (See Column 2, Line 52 to Column 3, Line 55). The tablets can comprise saccharides of various moldabilities, including mannitol, lactose, glucose, sucrose, lactitol, maltose, maltitol, and sorbitol (See Column 2, Lines 27-39). A lubricant, such as magnesium stearate, can be included in the tablets in amounts ranging from 0.1% to 2.0% by weight of the tablet (See Column 7, Lines 55-63). A disintegrant may be included as well, such as croscarmellose sodium and sodium starch glycolate (See Column 7, Line 64 to Column 8, Line 2). Other additives may also be included as well, such as colorants and sweeteners (See Column 8, Lines 29-45). The use of polyvinylpyrrolidone as a binder for the purpose of reducing the friability of a tablet is disclosed, and examples are given that illustrate how friability can be manipulated to below 1.0% (See Column 7, Lines 21-34; and Examples). In particular, Example 7 shows one set of tablets that exhibit a friability of about $2.7 \pm 2.2\%$, which the examiner will interpret to mean a range from about 0.5% to about 4.9%. In Example 8, Tablet B exhibits a friability of $0.8 \pm 0.5\%$. The limitations in Claim 1 regarding its ability to be packaged is interpreted to be directed toward a future intended use of the tablet, and is therefore not given any patentable weight. Claim 10 is directed toward a future intended use of the claimed tablet, and this limitation of intended use is not given patentable weight by the examiner. Therefore, the examiner considers the tablet of Claim 10 to be anticipated by the prior art.

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The Liu *et al.* patent does not explicitly teach methods of manufacturing tablets wherein the lubricant is entirely or mostly applied to the outer surface of the tablet.

The Schmitz *et al.* patent discloses a device that sprays powdered lubricants onto punches and dies of a tablet press. Such a device can be readily retrofitted into existing machinery and provide an improved method of tablet manufacture (See Column 1, Line 35 to Column 3, Line 36).

The Valentine patent is relied upon here as a teaching reference, stating that lubricants, having a particle size of 44 microns or less are known and desired within the art of manufacturing tablets. Furthermore, these lubricants may be further screened for smaller particle sizes (See Column 5, Line 54 to Column 6, Line 3).

The limitations of Claims 22, 32, 34, and 37-39 are not considered to be critical to the function of the instantly claimed invention, in view of the broad disclosure of the prior art. Absent a showing of criticality or of results that would be unexpected by one of ordinary skill in the art at the time the invention was made, these claims are not considered to be patentable above the prior art. The examiner also points out in Liu *et al.*, Column 4, Lines 35-48, there is a description of the moldability of various saccharides, which the examiner will interpret to read on various process conditions, particularly die diameters and compression pressures. Regarding Claims 27 and 37 in particular, the Schmitz *et al.* patent discloses the adherence of the powdered lubricant to the tablet press punch surfaces (See Column 2, Lines 10-24). It is the position of the examiner that in addition to adjusting operational parameters of the device disclosed in Schmitz *et al.*, it would also be obvious to one of ordinary skill in the art to influence lubricant adhesion

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to the punch surfaces by other factors, such as the selection of a particular lubricant, or its specific physical properties, such as particle size.

Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 01 March 2004 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The applicant has applied an overly stringent standard to what is fairly taught by the prior art. The prior art is relied upon for all that it contains, expressly, implicitly and inherently. See MPEP § 2106, 2111 and 2123. In the view of the examiner, it is sufficient that the Schmitz *et al.* patent broadly discloses the powdered lubricant spraying device to be a useful improvement in the tablet manufacturing art.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Finally, the examiner considers the phrases "to enable it to be removed with ease" and "designed to be packaged in blisters" to be recitations of intended use. It is unclear which

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particular claim limitations impart to the instantly claimed tablets the necessary structure and composition to possess such features. As these phrases are part of what the examiner considers to be recitation of intended use, they are not given patentable weight.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
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sj0

THURMAN K. PAGE
SERVISORY PATENT EXAMINER
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